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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,416	07/27/2001	Yukio Yamori	SAEGU85.001A	1599
20995	7590	06/27/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			ZUCKER, PAUL A	
			ART UNIT	PAPER NUMBER
			1621	

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,416

Applicant(s)

YAMORI ET AL.

Examiner

Paul A. Zucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 19-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 and 26-29 is/are allowed.
- 6) ☒ Claim(s) 11 and 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 May 2005 has been entered.

Current Status

2. This action is responsive to Applicants' amendment of 26 May 2005.
3. Receipt and entry of Applicants' amendment is acknowledged.
4. Claims 11 and 19-29 are pending.

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New Rejections

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claim Rejections - 35 USC § 103

5. Claims 11 and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizutani et al (Biochemical and Biophysical research Communications 1998,

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253, pages 859-863) in view of Caspar et al (WO 00/38620-A2 07-2000) and further in view of CN1127070 (07-1996, provided by Applicants).

Instantly claimed are food and pharmaceutical compositions comprising stilbene derivatives and methods for their use in treating and preventing the loss of bone due to osteoporosis and periodontal disease.

Mizutani teaches (Page 859, left column, first two sentences after abstract) that osteoporosis associated with estrogen deficiency after menopause is the most common cause of age related bone loss. Mizutani further teaches (Page 860, FIG.2, bottom right) the effect on ALP (Alkaline Phosphatase) activity of treatment of osteoblastic (bone forming) MC3T3-E1 cells with resveratrol (3, 4', 5-trihydroxystilbene, corresponding to instant formula (I)). Mizutani teaches (Page 859, right column, lines 10-13) that resveratrol (3, 4', 5-trihydroxystilbene, corresponding to instant formula (I)) is derived from grape cultivars (plants of the vitaceae family). Mizutani further teaches (Page 859, bottom right, last sentence) pharmaceutical compositions comprising 0.1% BSA, vehicle and/or varying amounts of resveratrol. Mizutani further specifically teaches (Page 862, left column, last sentence) using resveratrol for the prevention and treatment of osteoporosis. Implicit in this teaching is the idea that human individuals with osteoporosis, or at risk of developing same, must be identified.

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The difference between Mizutani and the instant invention is that Mizutani's teaching is limited to treatment of bone loss due to menopause while treatment of periodontal disease (alveolar bone loss) and use of resveratrol in foods is also instantly claimed.

Caspar, however, teaches (Page 2, line 12 – page 3, line 3) the use of resveratrol for the treatment of periodontal disease. Caspar further teaches (Page 5, line 3-page 8, line 9) pharmaceutical compositions comprising resveratrol. Caspar teaches (Page 5, line 15-19) rinses (mouthwash), sprays, pastes and gels as dosage forms as well.

The difference between the combined teachings of Mizutani and Caspar and the instant invention is that neither Mizutani nor Caspar teach the use of resveratrol in foods is also instantly claimed. Caspar is silent with respect to employing resveratrol in food compositions.

CN1127070, however, teaches (Abstract, lines 5 and 7-10) a composition in the form of food product (milk powder) comprising resveratrol (3, 4',5-trihydroxystilbene, corresponding to instant formula (I)). CN1127070 further teaches (Abstract, lines 7-10) is use in the treatment and prevention of coronary disease and osteoporosis.

The motivation would have been to incorporate the bone loss treatment disclosed by Mizutani along with the teachings of CN1127070 to turn compositions for the treatment of menopausal and alveolar bone loss into food products that would present a more attractive form of administration of the compositions and would lead

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to better patient compliance. There would have been a reasonable expectation for success would all limitations of the invention are taught by the references and all are directed to use of resveratrol.

Thus the instantly claimed compositions would have been obvious to one of ordinary skill in the art.

Examiner's Response to Applicants' Remarks with regard to this Rejection

6. Applicants have presented arguments with regard to this rejection. The Examiner responds to these below:
 - a. Applicants have argued that none of the recited prior art references disclose a limitation of "identifying a mammal having a need for increased bone breaking load and strength; and administering to said mammal at least one member selected from the compound of formula (1)" and that all the references exemplify only *in vitro* administration. Applicants further argue that in these references even remotely suggests that individuals having a need can be treated with a compound of Formula (1). The Examiner disagrees since Mizutani explicitly teaches (Page 862, left column, last sentence) that: "*Presumably, resveratrol is a useful tool in the prevention of and therapy for osteoporosis.*". Implicit is this teaching is that individuals in need of the prevention and treatment of osteoporosis be identified.
 - b. Applicants argue that CN 1127070 discloses a laundry list of components and numerous conditions that can be treated but does not relate to mammals having a need for increased bone breaking load and strength. The Examiner

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disagrees and points out that CN1127070 explicitly teaches (Abstract, lines 7-10) the use of its milk powder containing resveratrol in the prevention of osteoporosis which requires the identification of individuals in need thereof.

Applicant's arguments filed 26 May 2005 have been fully considered but they are not persuasive for the reasons presented above.

Conclusion


7. Claims 11 and 19-29 are pending. Claims 11 and 20-25 are rejected. Claims 19 and 26-29 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



PAULA ZUCKER, PH.D.
PRIMARY EXAMINER